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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,458	05/16/2006	Maria Antonia Vitiello	PRD2091US-PCT	3414
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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER RIGGS II, LARRY D	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,458

Applicant(s)

VITIELLO ET AL.

Examiner

Larry D. Riggs II

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, 41 and 42 are drawn to a method for selecting a panel of biomarkers for determining the stage of sepsis in an animal.

Group II, claim(s) 17-26, drawn to a method for providing survival prognosis and stage of sepsis for an animal diagnosed with sepsis.

Group III, claim(s) 27-31, drawn to a method of testing a compound for treating sepsis.

Group IV, claim(s) 32-40, drawn to a method and model system for determining a reference score for an infected group and effectiveness of a compound.

Group V, claim(s) 43-44, drawn to a method of treating sepsis.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The five different methods are directed to different results and thus necessarily have different modes of action.

Regarding Groups I and II, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. For example the method of Group I requires selecting a panel

of biomarkers associated with a stage of sepsis. Group II requires detecting a stage of sepsis and a prognosis of sepsis by analysis of sample data and scoring the data.

Regarding Groups I and III, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. For example the method of Group I requires selecting a panel of biomarkers associated with a stage of sepsis. Group III requires testing a compound for treating sepsis.

Regarding Groups I and IV, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. For example the method of Group I requires selecting a panel of biomarkers associated with a stage of sepsis. Group IV requires a model system and method of using the model system for determining scores of infected animal groups and effectiveness of a compound in treatment.

Regarding Groups I and V, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. For example the method of Group I requires selecting a panel of biomarkers associated with a stage of sepsis. Group V requires treating sepsis with a compound.

Regarding Groups II and III, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. Group II requires detecting a stage of sepsis and

a prognosis of sepsis by analysis of sample data and scoring the data. Group III requires testing a compound for treating sepsis.

Regarding Groups II and IV, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. Group II requires detecting a stage of sepsis and a prognosis of sepsis by analysis of sample data and scoring the data. Group IV requires a model system and method of using the model system for determining scores of infected animal groups and effectiveness of a compound in treatment.

Regarding Groups II and V, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. Group II requires detecting a stage of sepsis and a prognosis of sepsis by analysis of sample data and scoring the data. Group V requires treating sepsis with a compound.

Regarding Groups III and IV, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. Group III requires testing a compound for treating sepsis. Group IV requires a model system and method of using the model system for determining scores of infected animal groups and effectiveness of a compound in treatment.

Regarding Groups III and V, each process is limited to comprising distinct process steps not required by the other methods which define a special technical

feature that is unique to each method. Group III requires testing a compound for treating sepsis. Group V requires treating sepsis with a compound.

Regarding Groups IV and V, each process is limited to comprising distinct process steps not required by the other methods which define a special technical feature that is unique to each method. Group IV requires a model system and method of using the model system for determining scores of infected animal groups and effectiveness of a compound in treatment. Group V requires treating sepsis with a compound.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry D. Riggs II whose telephone number is 571-270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631

/Shubo (Joe) Zhou/
Shubo (Joe) Zhou, Ph.D.
Primary Examiner